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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Campbell Rogers, Elazer R. Edelman and Daniel I. Simon

Serial No.: 08/823,999

Group Art Unit: Not Yet Assigned

Filed: March 25, 1997

Examiner: Not Yet Assigned

For: MODULATION OF VASCULAR HEALING BY INHIBITION OF  
LEUKOCYTE ADHESION AND FUNCTION

Assistant Commissioner for Patents  
Washington, D.C. 20231

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INFORMATION DISCLOSURE STATEMENT  
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Sir:

Pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. § 1.97, applicants submit an Information Disclosure Statement, including six pages of Form 1449 and copies of the documents cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first office action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account No. 01-2507.

### United States Patents

<u>Number:</u>	<u>Issue Date:</u>	<u>Patentee:</u>	<u>Class/Subclass:</u>
4,244,946	01-13-1981	Rivier, et al.	424/177
4,305,872	12-15-1981	Johnston, et al.	260/112.5 R
4,316,891	02-23-1982	Guillemin, et al.	424/177
4,629,784	12-16-1986	Stammer	530/328
4,792,525	12-20-1988	Ruoslahti, et al.	435/240.243
4,868,116	09-19-1989	Morgan, et al.	435/240.2
4,980,286	12-25-1990	Morgan, et al.	435/172.3
5,567,435	10-22-1996	Hubbell, et al.	424/426

### Foreign Patent and Applications

<u>Number:</u>	<u>Publication Date:</u>	<u>Patentee/Applicant:</u>	<u>Country/Region:</u>
WO 93/01286	01-21-1993	Massachusetts Institute of Technology	PCT

### Publications

AGRAWAL, et al., "Oligodeoxynucleoside phosphoramidates and phosphorothioates as inhibitors of human immunodeficiency virus," *Proc. Natl. Acad. Sci. USA* 85(19):7079-7083 (1988).

ALTIERI, et al., "Oligospecificity of the Cellular Adhesion Receptor MAC-1 Encompasses an Inducible Recognition Specificity for Fibrinogen," *J. Cell Biol.* 107(5):1893-1900 (1988).

ALTIERI, et al., "The Structural Motif Glycine 190-Valine 202 of the Fibrinogen  $\gamma$  Chain Interacts with CD11b/CD18 Integrin ( $\alpha_M\beta_2$ , Mac-1) and Promotes Leukocyte Adhesion," *J. Biol. Chem.* 268(3):1847-1853 (1993).

ANDERSON, et al., "Contributions of the Mac-1 Glycoprotein Family and Adherence-Dependent Granulocyte Functions: Structure-Function Assessments Employing Subunit-Specific Monoclonal Antibodies," *J. Immunol.* 137(1):15-27 (1986).

ASKEW, et al., "Molecular Recognition with Convergent Functional Groups. Synthetic and Structural Studies with a Model Receptor for Nucleic Acid Components," *J. Am. Chem. Soc.* 111(3):1082-1090 (1989).

AULT, et al., "Cross-Reaction of a Rat-Anti-Mouse Phagocyte-Specific Monoclonal Antibody (ANTI-Mac-1) with Human Monocytes and Natural Killer Cells," *J. Immunol.* 126(1):359-364 (1981).

BLUME, et al., "Triple helix formation by purine-rich oligonucleotides targeted to the human dihydrofolate reductase promoter," *Nucl. Acids Res.* 20(7):1777-1784 (1992).

CLACKSON, et al., "Making antibody fragments using phage display libraries," *Nature*, 352(6336):624-688 (1991)

COONEY, et al., "Site-Specific Oligonucleotide Binding Represses Transcription of the Human *c-myc* Gene *in Vitro*," *Science* 241:456-459 (1988).

CROOKE, "Progress toward oligonucleotide therapeutics: pharmacodynamic properties," *FASEB J.* 7(6):533-539 (1993).

DAUGHERTY, et al., "Polymerase chain reaction facilitates the cloning, CDR-grafting, and rapid expression of a murine monoclonal antibody directed against the CD18 component of leukocyte integrins," *Nucl. Acids Res.* 19(9):2471-2476 (1991).

DIAMOND, et al., "The I Domain Is a Major Recognition Site on the Leukocyte Integrin Mac-1 (CD11b/CD18) for Four Distinct Adhesion Ligands," *J. Cell Bio.* 120(4):1031-1043 (1993).

DUVAL-VALENTIN, et al., "Specific inhibition of transcription of triple helix-forming oligonucleotides," *Proc. Natl. Acad. Sci. USA* 89(2):504-508 (1992).

ELLINGTON, et al., "*In vitro* selection of RNA molecules that bind specific ligands," *Nature* 346(6287):818-822 (1990).

ELLINGTON, et al., "Selected *in vitro* of single-stranded DNA molecules that fold into specific ligand-binding structures," *Nature* 355(6363):850-852 (1992).

FISCHMAN, et al., "A Randomized Comparison of Coronary-Stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease," *N. E. J. Med.* 331(8):496-501 (1994).

GRIGORIEV, et al., "A Triple Helix-forming Oligonucleotide-Intercalator Conjugate Acts as a Transcriptional Repressor via Inhibition of NF  $\kappa$ B Binding to Interleukin-2 Receptor  $\alpha$ -Regulatory Sequence," *J. Biol. Chem.* 267(5):3389-3395 (1992).

HOLT, et al., "An Oligomer Complementary to *c-myc* mRNA Inhibits Proliferation of HL-60 Promyelocytic Cells and Induces Differentiation," *Mol. Cell. Biol.* 8(2):963-973 (1988).

INOUE, et al., "Expression of Polymorphonuclear Leukocyte Adhesion Molecules and Its Clinical Significance in Patients Treated With Percutaneous Transluminal Coronary Angioplasty," *JACC* 28(5):1127-1133 (1996).

ITAKURA, et al., "Synthesis and Use of Synthetic Oligonucleotides," *Ann. Rev. Biochem.* 53:323-356 (1984).

KABAT, et al., Sequences of Proteins of Immunological Interest, 4th Ed. (U.S. Dept. Health and Human Services, Bethesda, MD 1987) (Title page and Table of Contents only).

LEWIS, et al., "Automated site-directed drug design: the concept of spacer skeletons for primary structure generation," *Proc. R. Soc. Lond.* 236:125-140 and 141-162 (1989).

MAHER, et al., "Inhibition of DNA Binding Proteins by Oligonucleotide-Directed Triple Helix Formation," *Science* 245:725-730 (1989).

McKINLAY, et al., "Rational Design of Antiviral Agents," *Ann. Rev. Pharmacol. Toxicol.* 29: 111-122 (1989).

MERRIFEILD, "Solid Phase Peptide Synthesis. I. The Synthesis of a Tetrapeptide," *J. Am. Chem. Soc.* 85:2149-2154 (1963).

MICKELSON, et al., "Leukocyte Activation With Platelet Adhesion After Coronary Angioplasty: A Mechanism for Recurrent Disease?" *JACC* 28(2):345-353 (1996).

MULLIGAN, "The Basic Science of Gene Therapy," *Science* 260:926-932 (1993).

NARANG, et al., "Chemical Synthesis of Deoxyigonucleotides by the Modified Triester Method," Methods Enzymol., Vol. 65, Chapter 61, pp. 610-620 (The Academic Press, New

York 1980).

OFFENSPERGER, et. al., "In Vivo inhibition of duck hepatitis B virus replication and gene expression by phosphorothioate modified antisense oligodeoxynucleotides," *EMBO J.* 12(3):1257-1262 (1993).

ORSON, et al., "Oligonucleotide inhibition of IL2R $\alpha$  mRNA transcription by promoter region collinear triplex formation in lymphocytes," *Nucl. Acids Res.* 19(12):3435-3441 (1991).

PEPINE, et al., "A Controlled Trial of Coricocosteroids to Prevent Restenosis After Coronary Angioplasty," *Circulation* 81(6):1753-1761 (1990).

PERRY, et al., "The Use of 3D Modelling Databases for Identifying Structure Activity Relationships," in QSAR: Quantitative Structure-Activity Relationships in Drug Design, (Fauchère, ed.) pp. 189-193 (Alan R. Liss, Inc. 1989).

PIETERSMA, et al., "Late Lumen Loss After Coronary Angioplasty Is Associated With the Activation Status of Circulating Phagocytes Before Treatment," *Circulation* 91(5):1320-1325 (1995).

POSTEL, et al., "Evidence that a triplex-forming oligodeoxyribonucleotide binds to the *c-myc* promoter in HeLa cells, thereby reducing *c-myc* mRNA levels," *Proc. Natl. Acad. Sci. USA* 88(18):8227-8231 (1991).

RIPKA, "Computers picture the perfect drug," *New Scientist* 1617:54-57 (1988).

ROGERS, et al., "Inhibition of Experimental Neointimal Hyperplasia and Thrombosis Depends on the Type of Vascular Injury and the Site of Drug Administration," *Circulation* 88(3):1215-1221 (1993).

ROGERS, et al., "Monocyte Recruitment and Neointimal Hyperplasia in Rabbits Coupled Inhibitory Effects of Heparin," *Art. Thromb. Vasc. Bio.* 16:1312-1318 (1996).

ROGERS, et al., "Endovascular Stent Design Dictates Experimental Restenosis and Thrombosis," *Circulation* 91(12):2995-3001 (1995).

ROUVINEN, et al., "Computer and Drug Design," *Acta Pharmaceutica Fennica* 97:159-166 (1988).

SARIN, et al., "Inhibition of acquired immunodeficiency syndrome virus by oligodeoxynucleoside methylphosphonates," *Proc. Natl. Acad. Sci. USA* 85(20):7448-7794 (1989).

SERRUYS, et al., "A Comparison of Ballon-Expandable-Stent Implantation with Balloon Angioplasty in Patients with Coronary Artery Disease," *N. E. J. Med.* 331(8):489-495 (1994).

SHAW, et al., "Modified deoxyoligonucleotides stable to exonuclease degradation in serum," *Nucleic Acids Res.* 19(4):747-750 (1991).

SZOSTAK, "In Vitro Genetics," *TIBS* 17:89-93 (1992).

WICKSTROM, et al., "Human promyelocytic leukemia HL-60 cell proliferation and *c-myc* protein expression are inhibited by an antisense pentadecadeoxynucleotide targeted against *c-myc* mRNA," *Proc. Natl. Acad. Sci. USA* 85(4):1028-1032 (1988).

YOUNG, et al., "Triple helix formation inhibits transcription elongation *in vitro*," *Proc. Natl. Acad. Sci. USA* 88(22):10023-10026 (1991).

ZAMECNIK, et al., "Inhibition of Rous sarcoma virus replication and cell transformation by a specific oligodeoxynucleotide," *Proc. Natl. Acad. Sci. USA* 75(1):280-284 (1978).

ZAMECNIK, et al., "Inhibition of replication and expression of human T-cell lymphotropic virus type III in cultured cells by exogenous synthetic oligonucleotides complementary to viral RNA," *Proc. Natl. Acad. Sci.*, 83(12):4143-4146 (1986).

ZHU, et al., "Systemic Gene Expression After Intravenous DNA Delivery Into Adult Mice," *Science* 261:209-211 (1993).


### Remarks

While this statement is believed to include all of the material presently known to applicants, it should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, applicants invite the Examiner to make an independent evaluation of the cited art to determine its materiality and relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably

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Filed: March 25, 1997  
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distinguish over the prior art referred to herein, either alone or in combination.

Respectfully submitted,

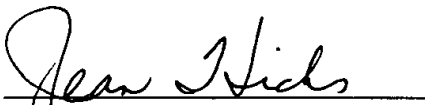
  
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Patrea L. Pabst  
Reg. No. 31,284

Date: April 27, 1998

ARNALL GOLDEN & GREGORY, LLP  
2800 One Atlantic Center  
1201 West Peachtree Street  
Atlanta, Georgia 30309-3450  
(404) 873-8794  
(404) 873-8795 (fax)

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Date: April 27, 1998